

Docket No. ASP-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Wu et al.	Confirmation No.:	8376
Appln. No.	:	09/746,990	Art Unit	: 1744
Filed	:	December 22, 2000	Examiner	: E.L. McKane
Title	:	APPARATUS AND METHOD FOR DELIVERING FLUIDS TO CONTACT SURFACES BETWEEN PARTS OF A MEDICAL DEVICE		

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**AMENDED APPEAL BRIEF**

## **I. Real Party in Interest**

The present application is assigned to Ethicon, Inc., a wholly owned subsidiary of Johnson & Johnson. The assignment documents are recorded at Reel 012254 Frame 0688.

## **II. Related Appeals and Interferences**

There are no related appeals or interferences.

## **III. Status of the Claims**

The case contains 28 claims. Claims 2, 3, 5, 11, 14, 18 and 19 have been cancelled. Claims 1, 4, 6 to 10 and 13 to 28 are pending in the application, and with the exception of claim 28 which has been indicated as being allowable, form the basis for this appeal. Each of these appealed claims stands rejected.

## **IV. Status of Amendments**

No amendments have been filed after the issuance of the Final Office Action.

## **V. Summary of the Claimed Subject Matter**

One aspect of the invention involves a medical device 60 comprising a first surface 64 and a second surface 64 which are adjacent to each other in facing relationship, rotatable with respect to one another about a pivot point 68 and which have a contact area therebetween adjacent the pivot point. (See Specification from page 11, line 26 to page 12, line 4. See also FIGS. 5, 6A and 6B.) A plurality of projections 70 on at least one of the two surfaces at the contact area are adapted to allow a fluid to flow around said projections thus enhancing cleaning and sterilization processes at the contact area. (See Specification at page 12, lines 1 to 17. See also FIGS. 5, 6A and 6B).

Another aspect of the invention involves a medical device 60 having at least two adjacent surfaces 64 in facing relation to each other with at least one contact area therebetween. A plurality of projections 70 on at least one of the two surfaces at the contact area are adapted to allow a fluid to flow around said projections thus enhancing cleaning and sterilization processes at the contact area. (See Specification at page 12, lines 1 to 17. See also FIGS. 5, 6A and 6B).

A method according to the claimed invention provides for cleaning, rinsing, scrubbing, disinfecting, or sterilizing a medical device having a first surface 64 and a second surface 64 adjacent to and in facing relation to reach other, which are rotatable with respect to one another about a pivot point 68 and which have a contact area therebetween at the pivot point. A plurality of projections 70 are provided on at least one of the surfaces at the contact area. (See Specification at page 12, lines 1 to 17. See also FIGS. 5, 6A and 6B). The method further provides for contacting the medical device with a fluid in a vessel, circulating the fluid in the vessel and contacting the medical device at the contact area with the fluid by flowing the fluid around the projections. (See Specification at page 16, lines 1 to 14). The fluid is selected from the group consisting of a cleaning fluid, a rinsing fluid, a scrubbing fluid, a disinfecting fluid, and a sterilizing fluid. (See Specification at page 15, lines 8 to 11).

## **VI. Grounds of Rejection to be Reviewed on Appeal**

- A. Claim 7 stands rejected under 35 U.S.C. §112, second paragraph.
- B. Claims 1, 4, 6, 13, 15, 21 and 23 to 25 stand rejected under 35 U.S.C. §102(b) over the Markham U.S. Patent No. 5,176,699.
- C. Claims 1, 4, 6, 13, 15 and 22 to 25 stand rejected under 35 U.S.C. §102(b) over the Sacker et al. U.S. Patent No. 5,776,146.
- D. Claims 8 and 9 stand rejected under 35 U.S.C. §103(a) over Markham or Sackier et al..

E. Claims 16, 17, 27 and 28 stand rejected under 35 U.S.C. §103(a) over Schad (WO 96/30058) in view of either Markham or Sackier et al.

F. Claim 20 stands rejected under 35 U.S.C. §103(a) over Williams U.S. Patent No. 5,447,684 over Markham or Sackier et al.

## **VII. Arguments**

**A. The rejection of claim 7 under 35 U.S.C. §112, second paragraph, was improper.**

The Examiner has rejected claim 7 under 35 U.S.C. §112, second paragraph on the reasoning that connector housings and luer locks lack first and second parts rotatable with respect to each other about a pivot. Applicants have amended the claim language to specify a pivot point, which a condition a luer lock clearly meets. The pivot point is the central axis of a luer lock fitting and there are contact surfaces adjacent this where the parts of the luer lock engage each other.

**B. The rejection of claims 1, 4, 6, 13, 15, 21 and 23 to 25 under 35 U.S.C. §102(b) over the Markham U.S. Patent No. 5,176,699 was improper.**

Markham fails to anticipate the claimed invention. The claims define first and second surfaces in facing relationship and a plurality of projections on at least one of the first or second surface. Markham discloses a pair of endoscopic forceps having gears to operate the forcep jaws. The surfaces in this instruments which are in facing relationship lack projections. The Examiner asserts that the gear teeth define projections but they are not on the surfaces in facing relationship, and further they are not adapted to allow a fluid to flow around them to enhance cleaning and sterilization of the facing surfaces. Accordingly, Markham fails to anticipate the claimed invention.

**C. The rejection of claims 1, 4, 6, 13, 15 and 22 to 25 under 35 U.S.C. §102(b) over the Sackier et al. U.S. Patent No. 5,776,146 was improper.**

Sackier et al. fail to anticipate the claimed invention. The claims define first and second surfaces in facing relationship and a plurality of projections on at least one of the first or second surface. Sackier et al. disclose a clamp having a ratchet mechanism.. The surfaces in this instruments which are in facing relationship lack projections. The Examiner asserts that the ratchet teeth define projections but they are not on the surfaces in facing relationship, and further they are not adapted to allow a fluid to flow around them to enhance cleaning and sterilization of the facing surfaces. Accordingly, Sackier et al. fail to anticipate the claimed invention.

**D. The rejection of claims 8 and 9 under 35 U.S.C. §103(a) over Markham or Sackier et al.. was improper.**

As discussed above, neither Markham or Sackier et al. teach opposing faces with projections thereon to enhance penetration of cleaning or sterilizing agents. They are just gears and ratchets. They do not explain the concepts of cleaning enhancement and would not make obvious the claimed invention to one of ordinary skill in the arts.

**E. The rejection of claims 16, 17, 27 and 28 under 35 U.S.C. §103(a) over Schad (WO 96/30058) in view of either Markham or Sackier et al. is improper.**

There is no suggestions for making the alleged combination yet even if made it would fail to reach the claimed invention. Schad appears singularly unsuited to cleaning either of the instruments depicted by Markham and Sackier et al. Schad holds a round instrument 10 in a holder 10 and then a rotating disk 17 rotates the instrument so that it can be sprayed on all sides. On of skill in the art would not be motivated to use such a device on the instruments of either Markham or Sackier et al.

Even if the alleged combination were made it would fail to reach the claimed invention. None of the references teach surfaces in facing relationship, at least one of which has projections thereon.

Claim 17

Claim 17 contains the further limitation of moving one of the two parts of the medical device during the cleaning. Shad changes the orientation of the entire device, but does not teach moving the parts of the device.

**F. The rejection of claim 20 under 35 U.S.C. §103(a) over Schad, Moyers and either Markham or Sackier et al. was improper.**

There is no suggestions for making the alleged combination yet even if made it would fail to reach the claimed invention. The problems of combining Shad with either Markam or Sackier et al. were discussed in subsection E. Even by adding a further reference the alleged combination fails to teach surfaces in facing relationship, at least one of which has projections thereon. Further, the alleged combination fails to teach reducing pressure in the vessel to thereby vaporize the fluid. Moyers does not draw a vacuum to vaporize fluid and does not draw sufficient vacuum for such purpose. Rather Moyers employs a vacuum line to move gases.

Applicants submit that the application is presently in condition for allowance and request favorable reconsideration and early notice of allowance. If it would speed prosecution, the Examiner is encouraged to contact Applicant's attorney at the telephone listed below.

Respectfully submitted,

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## CLAIMS APPENDIX

1. A medical device comprising a first surface and a second surface, the first surface and second surface being adjacent to each other in facing relationship, being rotatable with respect to one another about a pivot point and having a contact area therebetween adjacent the pivot point, said medical device being made up of at least one material, said medical device comprising a plurality of projections on at least one of the first surface and second surface at the contact area, and wherein said projections are adapted to allow a fluid to flow around said projections whereby to enhance cleaning and sterilization processes which employ the fluid.
2. (Cancelled)
3. (Cancelled)
4. The medical device of claim 1, wherein the medical device is reusable or disposable.
5. (Cancelled)
6. The medical device of claim 1, wherein the medical device is selected from the group consisting of a scissors, a forceps, a holder, a hemostat, and a rongeur.
7. The medical device of Claim 1, wherein said medical device comprises a connector housing or a luer lock.
8. The medical device of claim 1, wherein said at least one material is a metal or a non-metal.
9. The medical device of claim 8, wherein said metal is selected from the group consisting of stainless steel, titanium alloy, aluminum alloy, and nickel-chromium alloy.



10. The medical device of claim 8, wherein said non-metal is selected from the group consisting of polytetrafluoroethylene, nylon, polyolefin, liquid crystal polymer, polyester, silicon rubber, and styrenic thermoplastic.

11. (Cancelled)

12. (Cancelled)

13. A medical device comprising at least two adjacent surfaces in facing relation to each other with at least one contact area therebetween, said medical device being made up of at least one material, said medical device comprising a plurality of projections on at least one of said surfaces at the contact area, wherein said projections are adapted to promote flow of fluid between the surfaces at the contact area.

14. (Cancelled)

15. The medical device of claim 1, wherein said plurality of projections have a shape selected from the group consisting of points, lines, and a combination of points and lines.

16. A method of cleaning, rinsing, scrubbing, disinfecting, or sterilizing a medical device having a first surface and a second surface adjacent to and in facing relation to each other and which are rotatable with respect to one another about a pivot point and have a contact area therebetween at the pivot point, said method comprising; providing a plurality of projections on at least one of the first surface and second surface at the contact area; contacting said medical device with a fluid in a vessel; circulating said fluid in said vessel and contacting said medical device at the contact area with said fluid by flowing said fluid around the projections, said a fluid being selected from the group consisting of a cleaning fluid, a rinsing fluid, a scrubbing fluid, a disinfecting fluid, and a sterilizing fluid.

17. The method of claim 16, further comprising moving at least one of said at least two parts of said medical device during said cleaning, rinsing, scrubbing, or sterilizing said medical device.

18. (Cancelled)

19. (Cancelled)

20. The method of claim 16, further comprising reducing a pressure in said vessel, thereby vaporizing said fluid.

21. A medical device according to claim 1 having the projections on both the first part and the second part at the contact area.

22. A medical device according to claim 1 having the projections only on the first part.

23. A medical device according to claim 1 wherein the projections are formed by a series of grooves.

24. A medical device according to claim 23 wherein the grooves are parallel to each other.

25. A medical device according to claim 23 wherein the grooves are straight.

26. A medical device according to claim 23 wherein both the first part and the second part carry the grooves and wherein the grooves on the first part are in registry with the grooves on the second part.

27. A method according to claim 16 wherein the fluid cleans the first part and the second part at the contact area.

28. A method according to claim 16 wherein the fluid disinfects or sterilizes the first part and the second part at the contact area.

## EVIDENCE APPENDIX

[NONE]

RELATED APPEALS AND INTERFERENCED APPENDIX

[NONE]